

### **REMARKS**

Claims 1, 2, 4-8, 10-12, 17-21, 23, 24, 27, 28 and 33-46 are now pending in the application. Claims 9, 13-16, 22, 26, 29, 30, and 32 are canceled by this amendment. Claims 33-46 are added by this amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **REJECTIONS UNDER 35 U.S.C. § 103**

Claims 1, 2, 4-14, 16-18, 20-27, 29-30 and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Taylor et al. (U.S. Pat. No. 5,950,629) in view of Rapoport (U.S. Pat. No. 5,957,934). Claims 15, 19 and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Taylor et al. (U.S. Pat. No. 5,950,629) in view of Rapoport (U.S. Pat. No. 5,957,934) and Stark et al. (U.S. Pat. No. 5,823,975). These rejections are respectfully traversed.

Claims 9, 13-16, 22, 26, 29, 30, and 32 are canceled by this amendment, therefore, the rejections thereto are rendered moot.

#### **1. Prior Art**

Taylor et al. is directed to a system for assisting in surgery. The assistive system includes a coarse motion portion 12 and a fine motion portion 14. As is readily apparent throughout the figures, such as Fig. 1A and Fig. 10, the assistive system of Taylor et al. is both large and complex. For example, as illustrated in Fig. 1A, two motion portions are required, the coarse motion portion allows for motion in three directions, A, B, and C

and fine motion in the same three directions A', B', and C'. Moreover, the assisting system is based on a platform or jig separate from the patient and is not handheld.

Rapoport discloses shafts 30, 33 that interconnect with gears 26, 32 which are powered by motors 31, 34.

Stark et al. is directed to an orthopedic restraining device including a local monitoring system interconnected with a star nut.

## 2. Claim 1

Independent Claim 1 recites “a handheld advancer assembly operably connected to the guide unit; a thumb wheel advancer system connected to the handheld advancer assembly and located remote from the guide unit, a thumb wheel operable to be rotated around a thumb wheel axis, wherein the thumb wheel advancer system translates rotation of the thumb wheel about the thumb wheel axis into motion of the holder assembly”. Applicants respectfully submit that Taylor et al., Stark et al., or Rapoport, either singly or in combination, do not disclose or render obvious the claimed introducer device of independent Claim 1. For example, a handheld advancer seems to be contrary to either Taylor et al. or Rapoport. Taylor et al. discloses a large complex system having multiple drive portions and no handheld or thumb wheel portions. Rapoport discloses a headframe system having multiple motors and shafts to drive a gear. Neither of the references discloses a thumb wheel that is operable to be rotated or a system that translates the rotation movement to movement of the holder assembly. Therefore, independent Claim 1 is in condition for allowance. Further, each of the claims

that depend directly or indirectly from independent Claim 1 are also in condition for allowance.

### 3. Claim 17

Independent Claim 17 recites “a rotating wheel advancer . . . an MR compatible cable that operably couples the rotating wheel advancer to the holder assembly, where an input from the rotating wheel advancer controls motion of the holder assembly”. Again, Taylor et al. and Rapoport fail to disclose or render obvious a rotating wheel advancer or an MR compatible cable that allows input from a rotating wheel advancer to control motion of a holder assembly. Applicants respectfully disagree with the Office that Rapoport discloses a cable, much less an MR compatible cable. See Office action mailed July 12, 2007, p. 4, last paragraph. As recited in Rapoport, and noted in the Office Action, a gear 26 is rotated by a shaft 30 that is powered by a motor 31. These portions, illustrated in Fig. 5 of Rapoport, illustrate that the shaft extends from the motors and connects to the gears. Therefore, Rapoport does not disclose a cable, but rather discloses shafts that are driven by motors. Moreover, Applicants respectfully disagree with the Office’s assertion that the shafts of Rapoport must be MRI compatible. See *Id.* at p. 2, paragraph 2. Applicants submit Rapoport discloses the contrary. For example, Rapoport discloses that after MRI scans are taken, the patient is brought into surgery and based on the available MRI data, and other physical limitations, the physician will determine the optimum point of entry. See Rapoport, col. 4, lines 59-65. The markers positioned on the patient are operable to be received with a receiver in the operating room. See Rapoport, col. 5, lines 14-16 and 51-53. Therefore, Applicants

respectfully submit that the motor and shaft, illustrated in Fig. 5, are used during the operative procedure after images are taken. Accordingly, there is no disclosure in Rapoport for forming the shaft and motors of MRI compatible materials.

Taylor et al. does not disclose or suggest MR compatible components, as suggested by the Office. See Office Action mailed July 12, 2007, page 2. Taylor et al. discusses prior systems that can use images to direct a robot, but does not disclose that the robot is used while the images are being acquired. See Taylor et al., col. 2, lines 19-25. Moreover, Taylor et al. discloses that a second instrument can have means for transmitting an image of the patient's body (See Taylor et al., col. 5, lines 1-2), but does not disclose that the instrument is positioned within an imaging field while images, for example MRI images, are being acquired.

Finally, Applicants respectfully disagree with the Office's interpretation of Applicants amendments to the claims. See Office Action mailed July 12, 2007, page 2, paragraph 2. For example, independent Claim 1 originally recited "an MR compatible cable". The limitation of original Claim 1, which is similar to the limitation of current Claim 17, has been in the application since filed. Therefore, Applicants respectfully disagree that any amendments made to the claims could reasonably be interpreted to define that an MR compatible cable is obvious.

In light of the above, an MR compatible cable is not disclosed or taught in Rapoport or Taylor et al. In addition, neither Taylor et al. nor Rapoport discloses a system that is used while acquiring MRI images. Therefore, independent Claim 17, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

#### 4. Claim 24

Independent Claim 24 recites “an adjusting wheel system including an adjusting wheel coupled locally to the guide unit, wherein the adjusting wheel is operable to rotate around an axis of rotation and the adjusting wheel system translates the rotary motion of the adjusting wheel . . . into substantially linear motion of the holder assembly”. As discussed above, Applicants respectfully submit that neither Taylor et al. nor Rapoport disclose an adjusting wheel system. Applicants further submit that neither discloses a system that describes or renders obvious an adjusting wheel system that translates rotational motion into substantially linear motion. Independent Claim 24 also recites “a trajectory guide device and a fixation member, wherein the trajectory guide device is attached directly to a patient with the fixation member”. As discussed above, and clearly illustrated in Taylor et al., a trajectory device and a fixation member for fixing the trajectory guide device directly to a patient is neither anticipated nor rendered obvious. Taylor et al. discloses that the device sits on rails away from the patient. See Taylor et al. Fig. 1A and 10. Therefore, independent Claim 24, and each of the claims that depend directly or indirectly therefrom, is in condition for allowance.

#### **NEW CLAIMS**

New Claim 33 can find support in at least previously filed independent Claim 1, and Applicants respectfully submit that an MR compatible cable is not disclosed or rendered obvious by Taylor et al., Rapoport, or Stark et al., either singly or in combination.

New Claim 34 reciting “a cable having a first end attached to a first side of the thumb wheel and a second end attached to a second side of the thumb wheel, wherein the thumb wheel is rotated to move the cable in at least one of two directions” is also not disclosed or rendered obvious by Taylor et al. or Rapoport. Applicants respectfully submit that the recited structural configuration is not disclosed or rendered obvious by Taylor et al. or Rapoport. Therefore, dependent Claim 34 is also in condition for allowance.

New Claim 38 recites “a fixation member operable to fix the trajectory guide directly to a patient.” As discussed above, in relation to independent Claim 24, a fixation member to fix the trajectory guide directly to a patient is not anticipated or rendered obvious by Taylor et al., Rapoport, or Stark et al., either alone or in combination. As discussed above, the system of Taylor et al. is positioned away from the patient and sits on a rail or jig system. Therefore, dependent Claim 38 is also in condition for allowance.

New Claims 39-41 are added by this amendment, but do not add new subject matter and support for these claims can be found in at least previously pending Claims 30 and 32. Applicants respectfully submit that Taylor et al., Rapoport, or Stark et al. do not disclose or render obvious the method recited in these claims. For example, Applicants submit that attaching the guide unit to the patient, coupling the cable to a wheel advancer, and rotating the wheel advancer to form tension on at least one of the cable or the holder assembly is not disclosed or rendered obvious. Further, dependent Claim 41 recites “acquiring an image of a portion of the patient with the cable within the

portion of the patient being imaged . . . wherein the image . . . is unaffected by the cable.” As discuss above, such a system is not disclosed in Taylor et al. or Rapoport.

New Claims 42-45 are added by this amendment, but do not add new subject matter and support for these claims can be found in at least previously pending Claims 13-16. Applicants respectfully submit that Taylor et al., Rapoport, or Stark et al. do not disclose or render obvious the system recited in these claims. For example, Applicants submit that “an advancer assembly sized and configured to be held in a single hand of a user, including: . . . a thumb wheel advancer including a thumb wheel located remote from the guide unit” is not disclosed or rendered obvious. Applicants respectfully submit that an advancer assembly and a thumb wheel advancer, as recited in Claim 42, is not anticipated or rendered obvious. An advancer assembly to be held in a single hand and a thumb wheel advancer to be moved with the thumb of a single hand appears to be contrary to any of the devices described in Rapoport, Taylor et al. or Stark et al.

New Claim 46 is added by this amendment, support for which can be found throughout the application as filed, such as in Fig. 3 and 4 and paragraph 46. At least for the reasons indicated above, Claim 46 is in condition for allowance. Moreover, Claim 46 recites,

a handheld advancer assembly including: a pistol grip portion operable to be held within a hand of a user; . . . a thumb wheel operable to be moved with a thumb of the user; a trigger member operable to be actuated by a digit of the user . . . wherein movement of the thumb wheel is rotation around a thumb wheel axis; wherein the thumb wheel advancer system translates rotation of the thumb wheel about the thumb wheel axis into motion of the holder assembly along the range of motion.

New Claim 35 also recites, “the introducer device has a handheld pistol grip configuration”. Claims 36 and 37 also recite a pistol grip configuration. Applicants fail

to find such a system, including a pistol grip configuration, in any of Taylor et al., Rapoport, or Stark et al., either alone or in combination.


### CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: October 12, 2007

By:

  
Richard W. Warner, Reg. No. 38,043  
Michael L. Taylor, Reg. No, 50,521

HARNESS, DICKEY & PIERCE, P.L.C.  
P.O. Box 828  
Bloomfield Hills, Michigan 48303  
(248) 641-1600

RWW/MLT/srh